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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,639	03/07/2002	Walter Schuler	4-100-8303C/C1D1	8447

1095 7590 02/26/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/092,639	SCHULER ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The response filed on **12/4/08** has been entered.

2. Applicant's arguments filed 12/4/08 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

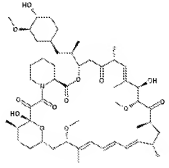
4. Claims 11-19 are pending in this office action and claims 20-28 are cancelled.

5. The rejection of claims 11-12, 15 and 17 under 35 U.S.C. 102(b) as being anticipated by Gregory et al., (US 5,283,257) is withdrawn because Gregory et al does not teach the species rapamycin claimed, even though Gregory teaches use of rapamycin generically, which is only different from Gregory's teaching by the substituent (2-hydroxy)ethyl.

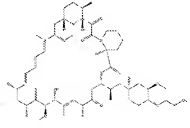
6. Claims 11-18 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al., (US 5,283,257) and Fraser-Smith et al., J. (1995) in view of Pichard et al. (1996), and Goldenberg, (US 5,364,612) and de Boer et al., (US 5,747,034) for the reasons made of record in Paper No. 20080529 and as follows.

Applicant argues that Gregory et al. do not teach the combination of cyclosporine A and FK-506 or any other combination (see remarks, page 4, mid section). Applicant also argues that Fraser-Smith fails to teach or add anything to the teaching of Gregory since Gregory's teaching is limited to the use of mycophenolate-mofetil and Pichard does not add anything to the dearth of the teaching by Gregory and Fraser, nor does Goldenberg and de Boer.

In response, the traversal is found not persuasive because Gregory specifically teaches a method of treating proliferation vascular disease by administering in



combination with rapamycin along with mycophenolic acid (as required by instant claim 11). Although the exact species of 40-O-(2-hydroxy)ethyl-



rapamycin is not taught by Gregory, nonetheless, the species taught by Gregory is known for the same function of treating proliferation of vascular injury. Therefore one of ordinary skill in the art would have been motivated to substitute Gregory's rapamycin with the claimed compound because substitutions of

methyl groups to ethyl groups are routinely practiced in the art, because the increase in the carbon chain of an alkane increases activity, as known to all chemists.

Also, all the agents cyclosporine A or G, or FK-506, CTLA4Ig, and CD monoclonals (including CD-3 monoclonals) have been employed in the treatment of disease conditions related to proliferation and restenosis (as discussed in the last office action) or used to inhibit proliferation of T-cells. Therefore, one of ordinary skill in the art would be motivated to combine the agents for the same treatment condition.

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art methods of using rapamycin and cyclosporine G or FK-506, CTLA4Ig, and CD1-8 individually for treating proliferative disease, it would have been obvious to combine the compounds for the treatment of neointimal proliferation of vascular injury because the idea of doing so would have logically flowed from these compounds having been individually taught in the prior art to be useful as therapeutic agents.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
2/19/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649